

## **REMARKS AND ARGUMENTS**

### **I. Patentability Arguments**

#### **A. The Rejections of Claims 44, 47-48 Under 35 U.S.C. §§ 102(e) over U.S. Patent 5,837,500 to Ladner ("Ladner 1") Should Be Withdrawn**

#### **B. Rejection over U.S. Patent No. 6,979,538, to Ladner (Ladner 2) Under 35 U.S.C. § 102(a or e) Should Be Withdrawn**

At page 2 of the advisory action, the Examiner maintained the rejection of claims 44 and 47-48 allegedly as being anticipated by Ladner US Patent No. 5,837,500 (Ladner 1) under 35 U.S.C. § 102(e). At page 3 of the advisory action, the Examiner reiterated the rejection of claims 44, 47-48, 61 and 62 allegedly as being anticipated by Ladner U.S. Patent No. 6,979,538 (Ladner 2) under 35 U.S.C. § 102(a or e). Applicants respectfully traverse the rejections and request reconsideration in view of the preceding amendments and following remarks.

Because the disclosures of Ladner 1 and Ladner 2 on which the Examiner relies for the rejections are identical, Applicants' arguments below apply to each of the two references.

The rejections in view of Ladner 1 and 2 appear to arise at least in part from the Examiner's opinion, set out at page 3 of the Advisory Action, that the claim language of claim 44 which recited "Fab antibody fragments" was either redundant or broadening the scope of the claim to include antigen-binding fragments such as  $V_H$ ,  $C_{H1}$  or  $C_{\gamma1}$ ,  $V_L$  and  $C_L$ . In response and for the purpose of clarification, Applicants amend claim 44 with this response and replace the phrase "Fab antibody fragments" with the phrase "Fab fragments of antibodies," which refers to a specific well-known, well-defined fragment of an antibody, the structure of which was known before the priority date of the present patent application. In fact, an Fab fragment of an antibody

is depicted in Figure 1 of the specification as filed (attached hereto as Exhibit A). Applicants have also submitted with a previous response, page 32 from the Penguin Dictionary of Biology (1994) that also depicts an Fab fragment of an antibody. As shown in each illustration, Fab fragments of antibodies have two polypeptide chains, one chain consisting of  $V_H$  and  $C_{H1}$  and the other chain consisting of  $V_L$  and  $C_L$  each of approximately two hundreds amino acids in length. Thus, as can be seen from the specification's Figure 1 and its description and the dictionary drawing, a "Fab fragment of an antibody" is a well defined and well known term which does not read on to scFv,  $V_H$  or  $V_L$  or fragments of an Fab.

In rejecting of the claims as anticipated by the Ladner references at page 2 of the advisory action, the Examiner alleges that Ladner 1 discloses an Fab fragment of an antibody in column 15. and at page 4 of the advisory office action, the Examiner alleges that Ladner 2 discloses an Fab fragment of an antibody in column 15.

The section in Column 15 of Ladner referenced to by the Examiner describes antibodies and antibody derivatives and Ladner's aversion to their use as binding proteins.

Normally, **the binding protein will not be an antibody or an antigen-binding derivative thereof.** An antibody is a cross-linked complex of four polypeptides (two heavy and two light chains). The light chains of IgG have a molecular weight of ~ 23,000 daltons and the heavy chains of ~ 53,000 daltons. A single binding unit is composed of the variable region of a heavy chain ( $V_H$ ) and the variable region of a light chain ( $V_L$ ), each about 110 amino-acid residues. The  $V_H$  and  $V_L$  regions are held in proximity by a disulfide bond between the adjoining  $C_L$  and  $C_{H1}$  regions; altogether, these total 440 residues and correspond to an Fab fragment. Derivatives of antibodies include Fab fragments and the individual variable light and heavy domains.

At pages 3 and 4 of the office action, the Examiner recites case law that supports a statement that a patent is relevant as prior art for all it contains, including non-preferred embodiments. However, regardless of whether or not antibodies or derivatives thereof are a non-

preferred embodiment, the references still fail to disclose the presently claimed invention and thus cannot properly anticipate the claims.

In order to anticipate the present invention, the law requires that every element of the claimed invention must be identically shown in a single reference. In Re Bond, 910 F.2d 831, 832 (Fed. Cir. 1990) *citing Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988). These elements must be arranged as in the claims under review. Id., *citing Lindemann Machinfabrik v. American Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *see also Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

As set out in amended Claim 44, the present invention is directed to:

44. A method of obtaining a member of a specific binding pair, the method comprising:

providing a library of in vitro mutagenized nucleic acid from an existing antibody coding sequence,

producing a library of filamentous bacteriophage particles displaying a population of specific binding pair members which comprise a binding domain of an immunoglobulin, each particle containing nucleic acid from the library of in vitro mutagenized nucleic acid from an existing antibody coding sequence,

contacting the library of filamentous bacteriophage particles with a desired epitope,  
and

separating particles displaying specific binding pair members comprising a binding domain which binds to said epitope,

wherein the specific binding pair members are Fab fragments of antibodies.

Neither Ladner 1 nor Ladner 2 can properly anticipate claims 44, 47-48, 61 and 62 of the present application because, **they do not recite every element of the presently claimed invention arranged as in the presently pending claims as is required** by the law. More

specifically, the references fail to disclose, *inter alia*, a method of obtaining a member of a specific binding pair which requires producing a library of filamentous bacteriophage particles displaying Fab fragments of antibodies as set out in claim 44 and its dependent claims. In view of their failure to disclose all of the elements of the claim arranged as in the present claims, the rejection over Ladner 1 under 35 U.S.C. §102(e) and the rejection over Ladner 2 under 35 U.S.C. §102(a or e) may be properly withdrawn and withdrawal is requested.

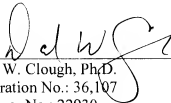
### Conclusion

In view of the above amendments and remarks, Applicants respectfully submit that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the (312) 595-1408.

Respectfully submitted,

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# **EXHIBIT 1**